

REMARKS

Claims 1-23 are pending. Applicants have previously canceled Claims 11-14. Claims 1-10 and 15-23 are under consideration. With the entry of this Response, Applicants have amended Claims 1, 3, 7, 8, 15, and 18.

The support for the amendment to Claim 1 is found in the specification at least in paragraph [0018] of Applicants' published patent application (US 2005/0256539).

The support for the amendment to Claim 3 is found in the specification at least in paragraph [0019] of Applicants' published patent application (US 2005/0256539).

The support for the amendment to Claim 7 is found in the specification at least in paragraph [0019] of Applicants' published patent application (US 2005/0256539).

The support for the amendment to Claim 8 is found in the specification at least in paragraph [0020] of Applicants' published patent application (US 2005/0256539).

The support for the amendment to Claim 15 is found in the specification at least in paragraph [0022] of Applicants' published patent application (US 2005/0256539).

The support for the amendment to Claim 18 is found in the specification at least in paragraph [0022] of Applicants' published patent application (US 2005/0256539).

With the entry of this Response, Applicants have added Claims 22-23. Support the new Claims 22-23 can be found in the specification at least in paragraphs [0016], [0024], [0037], and [0053] and in Figure 1.

Claims 1, 3, 8, and 15 are independent claims. In view of the following remarks directed at these independent claims, Applicants respectfully request the reconsideration and allowance of Claims 1-10 and 15-23.

35 U.S.C. § 103 REJECTION

The Office Action rejected Claims 1-10 and 15-21 as being obvious over Rohan *et al.* (U.S. Patent No. 6,572,528) in view of Fox *et al.* (U.S. Patent No. 7,087,008). The Office Action stated that "it would have been obvious to use the fMRI of Fox to help position the magnets for TMS in order to properly locate and stimulate the desired area of the patient's brain to enhance cognitive performance, as taught by Rohan." (Office Action, p. 2). Applicants traverse this rejection to the extent that the rejection applies to the claims as amended.

Under 35 U.S.C. § 103(a), the Office bears the burden of establishing a *prima facie* case of obviousness. A *prima facie* case of obviousness requires: (1) that there be a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the teachings of reference or to combine the teachings of multiple references; (2) that there be a reasonable expectation of success; and (3) that the prior art reference, or references when combined, teach or suggest all of the elements of the claim. (See, e.g., M.P.E.P § 2143). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and cannot be based on Applicants' disclosure. (See, e.g., *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); *In re Fine*, 87 F.2d 1071, 1074 (Fed. Cir. 1988)). Furthermore, rejections based on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be explicit analysis including some rational underpinning to support the legal conclusion of obviousness. (*K.S.R. Int'l Co. v. Teleflex, Inc.*, 550 U.S. 14 (2007) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006))). If the references do not teach each and every claimed element, then a finding of obviousness fails.

Applicants respectfully submit that the combination of Rohan and Fox does not render as obvious Applicants' currently pending claims. In the discussion that follows, Applicants are not arguing against the references individually, as the Office Action relied on a combination of references to support the obviousness rejection. Rather, in the discussion that follows, Applicants are merely highlighting the failure of the cited references to teach or suggest each and every claimed element, which is a necessary predicate to maintaining the obviousness rejection.

Independent Claim 1

Regarding Applicants' independent Claim 1, the Office Action stated that "Rohan teaches that TMS can be used to enhance cognitive performance . . . [and] that selection for treatment can be based upon learning difficulties and memory impairments." (Office Action, p. 2, citing Col 2, l. 9 and Col. 3, l. 52). Applicants note that Rohan is directed to "improving the condition of individuals with cognitive disorders, such as ***depression***" (Abstract) (emphasis added). Rohan explains that a subject can self-select for enhanced brain function using either subjective or objective criteria including "***anxiety, moodiness, depression, lethargy, sleepiness, learning difficulties, and memory impairments.***" (Col. 3, ll. 52-55) (emphasis added).

In the only example provided, Rohan explains that “twenty-one people exhibiting symptoms of *depression* were selected by medical professionals and subjected to the present method.” (See Example, Col. 5, ll. 64-66) (emphasis added). Rohan used a 1.5 Tesla MRI scanner to generate a “magnetic field [that] induced an electric field in the brains of the subjects.” (Col. 6, ll. 36-37). Rohan reports the results of this experiment in Figure 7, which shows a total of forty-three post-treatment visits by the twenty-one subjects. On twenty-two visits, the subject reported an improved mood. In the remaining twenty-one visits, subjects reported either no improvement in mood or a worsening of mood. (Figure 7).

However, Rohan fails to teach or suggest the elements for which it was cited. Specifically, Rohan fails to teach or suggest step (d) of Applicants’ currently pending Claim 1, which recites “effectuating a change in the performance of the predetermined task by the subject.” Rather, Rohan performs non-localized MRI on the head of a depressed subject and then records the mood of the subject. Rohan does not teach or suggest that the subject perform a predetermined task as currently claimed.

Furthermore, Rohan does not teach or suggest the localization of the magnetic field or the electric field to any particular portion or section of the brain. As Rohan fails to teach or suggest step (a) of Applicants’ currently pending Claim 1, the Office Action cited Fox for the teaching “that a model or maps of the functional state of the brain are computed in order to determine optimal placement of the coils to stimulate the brain using TMS.” (Office Action, p. 2). Applicants respectfully submit that Fox does not make up for the deficiencies of Rohan.

Therefore, Rohan and Fox, whether considered individually or in combination with each other, fail to teach or suggest each and every element of Claim 1 as currently amended. Furthermore, the skilled person would recognize that this combination fails to result in the currently claimed method of using transcranial magnetic stimulation to change the performance of a subject. Accordingly, the combination of Rohan and Fox fails to render as obvious Claim 1. As Claim 2 depends from Claim 1, and “dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious” (*In re Fine*, 5 U.S.P.Q. 2d 1569, 1600 (Fed. Cir. 1988)), the combination of Rohan and Fox also fails to render as obvious Claim 2. Applicants respectfully request that the Examiner withdraw this rejection and allow Claims 1-2.

Independent Claim 3

Regarding Applicants' independent Claim 3, the Office Action stated that "to use a control group is a standard practice in medical studies in order to determine if the procedure works as desired." (Office Action, p. 2). As Claim 3 does not recite "control group" or describe a "control group" or "control conditions", Applicants respectfully submit that the Office Action has mischaracterized Claim 3. Rather, Claim 3 recites "(a) dividing the plurality of subjects into groups" and "(b) subjecting *each of the groups* into a first and second state". (emphasis added). This is not the equivalent of a "control group" as suggested by the Office Action.

Furthermore, as Rohan teaches the treatment of depression in subjects, Rohan fails to teach or suggest step (f) of Applicants' currently pending Claim 3, which recites "effectuating a change in the performance of the predetermined task by the subject" As discussed above, because Rohan also fails to teach or suggest step (c) of Applicants' currently pending Claim 3, the Office Action cited Fox for the teaching "that a model or maps of the functional state of the brain are computed in order to determine optimal placement of the coils to stimulate the brain using TMS." (Office Action, p. 2). Applicants respectfully submit that Fox does not make up for the deficiencies of Rohan.

Therefore, Rohan and Fox, whether considered individually or in combination with each other, fail to teach or suggest each and every element of Claim 3 as currently amended. Furthermore, the skilled person would recognize that this combination fails to result in the currently claimed method of using transcranial magnetic stimulation to change the performance of a plurality of subjects. Accordingly, the combination of Rohan and Fox fails to render as obvious Claim 3. As Claims 4-7 depend from Claim 3, and "dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious" (*In re Fine*, 5 U.S.P.Q. 2d 1569, 1600 (Fed. Cir. 1988)), the combination of Rohan and Fox also fails to render as obvious Claims 4-7. Applicants respectfully request that the Examiner withdraw this rejection and allow Claims 3-7.

Independent Claim 8

Regarding Applicants' independent Claim 8, the Office Action stated that "fMRI encompasses a behavior individualized imaging of the patient's brain." (Office Action, p. 3). As

Rohan teaches the treatment of depression in subjects, Rohan fails to teach or suggest step (e) of Applicants' currently pending Claim 8, which recites "affecting the behavior related to the at least one cognitive neural circuit." As discussed above, the Office Action cited Fox for the teaching "that a model or maps of the functional state of the brain are computed in order to determine optimal placement of the coils to stimulate the brain using TMS." (Office Action, p. 2). Applicants respectfully submit that Fox does not make up for the deficiencies of Rohan.

Therefore, Rohan and Fox, whether considered individually or in combination with each other, fail to teach or suggest each and every element of Claim 8 as currently amended. Furthermore, the skilled person would recognize that this combination fails to result in the currently claimed method of using transcranial magnetic stimulation to affect the behavior of at least one subject. Accordingly, the combination of Rohan and Fox fails to render as obvious Claim 8. As Claims 9-10 depend from Claim 8, and "dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious" (*In re Fine*, 5 U.S.P.Q. 2d 1569, 1600 (Fed. Cir. 1988)), the combination of Rohan and Fox also fails to render as obvious Claims 9-10. Applicants respectfully request that the Examiner withdraw this rejection and allow Claims 8-10.

Independent Claim 15

Regarding Applicants' independent Claim 15, the Office Action stated that "Fox teaches that a model can be made of the patient's brain including a functional-image derived[] model." (Office Action, p. 3, citing Col. 5, l. 33 in Fox). The Office Action also stated that storing "a variety of functional models or maps in order to correctly position the arm of the magnetic stimulation would help facilitate the efficient use of the device. Col. 5:45 of Fox teaches that such a model or map can be store for subsequent use." (Office Action, p. 3). Lastly, the Office Action stated that Rohan teaches portability. (Office Action, p. 3, citing Col. 3 in Rohan).

Rohan teaches that "the magnetic coil can be included in a hat-like structure, and the wave-form generator, amplified, and power source (e.g., a battery) integrated into a control mechanism that the subject carries or wears, i.e., on his or her subject's belt." (Col. 3, ll. 35-39). Fox discusses the co-registering of brain surface models to created a conjoined model. (Col. 5, ll. 32-36). However, Rohan and Fox fails to teach or suggest several claimed elements. For

example, the combination of Rohan and Fox fails to teach or suggest *at least* the following claimed elements:

- “a CPU”;
- “a database in communication with the CPU”;
- “a movable electromagnetic coil electrically coupled to the energy source and in communication with the CPU”;
- “wherein when the subject is to perform a predetermined task, the CPU selects one or more fMRI maps of one or more neural circuits corresponding to the predetermined task from the database and causes the movable electromagnetic coil to be positioned over a region on the scalp of the subject”; and
- “wherein the movable electromagnetic coil delivers transcranial magnetic stimulation to the region on the scalp and effectuates a change in the performance of the predetermined task by the subject.”

Applicants respectfully submit that Fox does not make up for the deficiencies of Rohan.

Therefore, Rohan and Fox, whether considered individually or in combination with each other, fail to teach or suggest each and every element of Claim 15 as amended. Furthermore, the skilled person would recognize that this combination fails to result in the currently claimed portable system for using transcranial magnetic stimulation to change the performance of at least one subject. Accordingly, the combination of Rohan and Fox fails to render as obvious Claim 15. As Claims 16-21 depend from Claim 15, and “dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious” (*In re Fine*, 5 U.S.P.Q. 2d 1569, 1600 (Fed. Cir. 1988)), the combination of Rohan and Fox also fails to render as obvious Claims 16-21. Applicants respectfully request that the Examiner withdraw this rejection and allow Claims 15-21.

CONCLUSION

Applicants believe that the foregoing is a complete response to the Non-Final Office Action mailed December 30, 2009. Applicants respectfully submit that at least Claims 1-10 and 15-23 are patentable. Early and favorable consideration is solicited. If the Examiner believes there are other issues that can be resolved by a telephone interview, or that there are informalities that remain in the application that may be corrected by the Examiner’s amendment, then a telephone call to the undersigned attorney at (678) 420-9366 is respectfully solicited.

With this Amendment and Response, Applicants also enclose a Petition for an Extension of Time to extend the period of response by three-months, *i.e.*, to June 30, 2010, and a credit card payment. The credit card payment is in the amount of \$555, which is the small entity fee pursuant to 37 C.F.R. § 1.17(a)(3) for a three-month extension of time. Applicants believe that this is the correct amount due; however, Applicants authorize the Commissioner to charge to Deposit Account No. 14-0629 any additional fees that may be required, or to deposit into the same account any overpayment of fees.

Respectfully submitted,

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